



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,211	12/08/2005	Wridzer Jan Willem Bakker	2003.817US	1246
67706	7590	02/03/2011		
ORGANON USA, INC. c/o MERCK 2000 Galloping Hill Road Mail Stop: K-6-1, 1990 Kenilworth, NJ 07033			EXAMINER KASSA, TIGABU	
			ART UNIT 1619	PAPER NUMBER
			NOTIFICATION DATE 02/03/2011	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@spcorp.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,211	<b>Applicant(s)</b> BAKKER ET AL.	
	<b>Examiner</b> TIGABU KASSA	<b>Art Unit</b> 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 18-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Request for Continued Examination**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/18/2011 has been entered.

### **Formal Matters**

Applicants' amendment filed 07/06/2010 is acknowledged and entered. **Claims 1-15 and 17-20 are currently pending. Claims 1-12 and 18-20 are under consideration in the instant office action.** Claims 13-15 and 17 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claims. Claim 16 is cancelled.

Applicant's remarks have been fully considered and they necessitate new grounds of rejection. Accordingly, this Office Action is non-final. Rejections not specifically addressed herein have been withdrawn.

### **New Rejections**

#### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 1619

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

**All prior art references are cited previously in the record except Nakashima (US Patent No. 5326484).**

**Claims 1-3, 5-8, 10, 18 and 20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jakupovic (US Patent No. 6,221,398, IDS reference), Subramniam (US Patent No. 6,113,795), and Nakashima (US Patent No. 5326484).**

### **Applicant Claims**

Applicant claims an antisolvent solidification process for preparing a solid composition comprising at least one organic or inorganic compound, wherein a liquid medium comprising at least one dissolved organic or inorganic compound is forced through a membrane which is positioned in a membrane module into one or more antisolvent or wherein one or more antisolvent are forced through a membrane which is positioned in a membrane module into a liquid medium comprising at least one organic or inorganic compound, and whereby the process is carried out as a continuous process and the membrane has up to 3  $\mu\text{m}$  pore size and the shape of the membrane is selected from tubes, fibers, and spiral wounds, yielding a composition comprising solid particles comprising said organic and/or inorganic compound(s).

### **Determination of the Scope and Content of the Prior Art (MPEP §2141.01)**

Jakupovic teaches a process for producing a pharmaceutical powder for inhalation comprising crystalline particles of an inhalation compound, comprising dissolving an inhalation compound to be provided in crystalline particle form in a solvent; and introducing the solution containing the inhalation compound, in droplet form or as a jet stream into an anti-solvent which is miscible with the solvent and which is under agitation, under non-supercritical conditions (column 2, lines 26-34). Jakupovic teaches that once the compound is dissolved the solution is preferably added to the antisolvent through **a porous filter** having pores of 10-160 microns (column 4, lines 24-27). This teaching reads on the limitation reciting forcing the liquid medium through a membrane. Jakupovic teaches an illustrative example where a solution of budesonide in methanol was added to water/ice at a rate of 1 ml/min, through a glass filter with a porosity of 40-90 microns, and with stirring with ultraturrax equipment. The obtained slurry contained

Art Unit: 1619

**budesonide** crystalline particles of MMD 2.79 microns. 90% of the particles had a diameter of below 6.0  $\mu\text{m}$  (column 5, lines 20-26, example 2). Jakupovic teaches a list of medically useful compounds which may be provided in respirable particle form such as  $\beta$ 2-adrenoteceptor agonists, glucocorticosteroids like budesonide etc (column 3, lines 8-32). Jakupovic disclose the process may be used to prepare **carbohydrates (saccharides)** such as lactose, dextrose, melezitose, maltose, mannitol, trehalose and raffinose, as well as salts of fatty acids, bile salts, phospholipids and alkyl glycosides, which may be useful as penetration enhancers (column 3, lines 45-50). Furthermore, Jakupovic teaches the pharmaceutically acceptable additive may be prepared in the same manner as the medically useful compound, and the powders may then be mixed together, or a powder containing the medically useful compound and additive may be prepared in certain cases, i.e. when the compound and additive have similar solubilities, by dissolving all of the desired substances together in the solvent (column 3, lines 50-57).

**Ascertainment of the Difference between Scope the Prior Art and the Claims  
(MPEP §2141.012)**

Jakupovic do not teach the membrane having up to 3  $\mu\text{m}$  pore size and the shape of the membrane being tubes, fibres, and spiral wounds. These deficiencies are cured by the teachings of Subramniam and Nakashima.

Subramniam teaches processes and apparatuses that are provided for continuously harvesting particles from organic solution-laden near-critical and supercritical fluids. Broadly, the processes and apparatuses utilize a filter or separator comprising a thin membrane supported on a sintered stainless steel tube (see abstract). A feed stream comprising the desired particles, a

Art Unit: 1619

supercritical antisolvent for the particles (preferably CO<sub>2</sub>), and a solvent for the particles, is contacted with the membrane layer of the filter under supercritical conditions for the mixture of antisolvent and solvent (see abstract). The desired particles are retained by the filter while the solvent and most of the antisolvent pass through the filter, resulting in separation of the particles from the solvent (see abstract). Subramniam teaches the separator comprises first and second porous layers (column 3, lines 31-32). Subramniam teaches the first layer is formed as a membrane, the membrane preferably includes pores having an average pore size of from about 0.08-0.12  $\mu\text{m}$ , and preferably about 0.1  $\mu\text{m}$  (column 3, lines 46-49). Subramniam teaches that those skilled in the art will appreciate that the average pore size can be adjusted to suit the particular application (column 3, lines 49-51). For example, the membranes can be selected for retaining particles having the following desired particle sizes: particles having an average size of less than about 0.5  $\mu\text{m}$  for use in forming cancer treating agents or for use in intravenous injections; particles having an average size of from about 1-5  $\mu\text{m}$  for use in inhalation therapy; and particles having an average size of from about 10-50  $\mu\text{m}$  for applications where larger particles sizes are necessary (column 3, lines 51-59).

Nakashima, in claim 1, teach a method of producing an o/w type monodisperse single emulsion which comprises introducing under pressure a dispersed phase-forming oily liquid into an aqueous continuous phase liquid containing a cationic surfactant through **a hydrophilic porous glass membrane** positively charged by surface **treatment and having pores uniform in size at a pressure 1 to 10 times the critical pressure.** It is clear from the teachings of Nakashima et al., a porous glass membrane can resist pressure effects while forcing through liquid solutions and producing uniform particles. Nakashima teaches monodisperse single

emulsions which have a mean emulsion **particle size within the range of 0.3 to 40  $\mu\text{m}$**  (see abstract). Additionally, the porous glass membrane filters can also assume different shapes for instance Nakashima teaches cylindrical porous glass membrane filters (see example 4 and the whole document).

**Finding of Prima Facie Obviousness Rationale and Motivation  
(MPEP §2142-2143)**

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the process of Jakupovic by using a membrane having up to 3  $\mu\text{m}$  pore size and the shape of the membrane is selected from tubes, fibres, and spiral wounds, because Subramniam teaches the use of such membranes for filtration for a similar process as described above for the preparation of solid crystal particles. The skilled artisan would have been motivated to use a membrane having up to 3  $\mu\text{m}$  pore size and the shape of the membrane is selected from tubes, fibres, and spiral wounds in such a process, because Subramniam teaches that those skilled in the art will appreciate that the average pore size can be adjusted to suit the particular application (column 3, lines 49-51). For example, the membranes can be selected for retaining particles having the following desired particle sizes: particles having an average size of less than about 0.5  $\mu\text{m}$  for use in forming cancer treating agents or for use in intravenous injections; particles having an average size of from about 1-5  $\mu\text{m}$  for use in inhalation therapy; and particles having an average size of from about 10-50  $\mu\text{m}$  for applications where larger particles sizes are necessary (column 3, lines 51-59).



Furthermore, it would have been prima facie obvious to substitute the porous glass filter of Jakupovic for a membrane of Subramniam with the potential to withstand the pressure drop over the membrane when used as a dosing device through which liquid medium or antisolvent is forced because Nakashima, in claim 1, teach a method of producing an o/w type monodisperse single emulsion which comprises introducing under pressure a dispersed phase-forming oily liquid into an aqueous continuous phase liquid containing a cationic surfactant through **a hydrophilic porous glass membrane** positively charged by surface **treatment and having pores uniform in size at a pressure 1 to 10 times the critical pressure.** The teachings of Nakashima show that a porous glass membrane can resist pressure effects while forcing liquid solutions through to producing uniform particles. Nakashima teaches monodisperse single emulsions which have a mean emulsion **particle size within the range of 0.3 to 40  $\mu\text{m}$**  (see abstract). Additionally, the porous glass membrane filters can also assume different shapes for instance Nakashima teaches cylindrical porous glass membrane filters (see example 4 and the whole document).

With regard to the limitation reciting the process being continuous, Subramniam teaches as described above a continuous process, furthermore, the skilled artisan would also consider the process described by Jakupovic as being necessarily a continuous process. A skilled artisan would have had a reasonable expectation of success in combining the references, because all of the references address similar process of preparing solid microparticles.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

**Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jakupovic (US Patent No. 6,221,398), Subramniam (US Patent No. 6,113,795), Nakashima (US Patent No. 5326484), and Nocent (J. Pharm. Sci, 90, 1620-1627).**

#### **Applicant Claims**

The claimed subject matters of instant claim 1 are set forth above. Instant claim 4 recites a process according to claim 1 wherein an emulsion is formed before said composition comprising solid particles is obtained.

#### **Determination of the Scope and Content of the Prior Art (MPEP §2141.01)**

The teachings of Jakupovic, Subramniam, and Nakashima are set forth above.

#### **Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)**

Jakupovic does not explicitly teach a process of forming an emulsion before solid particles are formed. This deficiency is cured by the teachings of Nocent.

Nocent teaches quasi-emulsion solvent diffusion method where “the drug is dissolved in solvent and the antisolvent phase (antisolvent and emulsifier) are prepared separately and maintained at different temperatures. Nocent also teaches that the crystallization process incorporating the emulsifier is attractive because it can lead to significant improvements in the

Art Unit: 1619

physical properties of materials, such as flowability, compressibility and compactibility (see page 1620). The solvent solution is then added to the antisolvent solution under agitation. Since interactions between drug and solvent being stronger than the interactions between solvent and antisolvent, the solvent is dispersed in the antisolvent and creates a quasi-emulsion. The formation of this unstable emulsion is induced by the increase in the interfacial tension between solvent and antisolvent. However, since emulsifier is added the emulsion is formed resulting in the solvent and antisolvent diffusing in opposite directions, specially the antisolvent diffusing into the droplets, reducing the solubility of the drug and inducing crystallization inside the droplets” (see page 1621).

**Finding of Prima Facie Obviousness Rationale and Motivation**  
(MPEP §2142-2143)

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention to modify the teachings of Jakupovic via the formation of an emulsion, because Nocent teaches a similar process of crystallization where a drug is dissolved in solvent and added to the antisolvent in the presence of an emulsifier to form an emulsion resulting in crystal particles of the drug. An ordinary skilled artisan would have been motivated to form an emulsion, because Nocent teaches that the crystallization process incorporating the emulsifier is attractive because it can lead to significant improvements in the physical properties of materials, such as flowability, compressibility and compactibility (see page 1620). Thus, an ordinary skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings, because all of the cited references teach similar processes of crystallization of chemical compounds using the solvent/antisolvent system, specifically, Nocent’s process

utilizing the addition of an emulsifier demonstrated to be useful during the crystallization process to form a stable emulsion form from the unstable quasi-emulsion formed as a result of interactions between drug and solvent being stronger than the interactions between solvent and antisolvent (see page 1621).

**Claims 1, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jakupovic (US Patent No. 6,221,398), Subramniam (US Patent No. 6,113,795), Nakashima (US Patent No. 5326484), and Chen (US Patent No 7,374,779) and as evidenced by Nakagawa (Japan J. Pharmacol. 29, 509-514, 1979).**

#### **Applicant Claims**

The claimed subject matters of instant claims 1 and 8 are set forth above. Instant claim 9 recites a process according to claim 8, wherein the inorganic or organic pharmaceutical compound is 3-ketodesogestrel as per applicant's species election. Examiner also acknowledges that the species election for the pharmaceutical compound type is expanded to progesterone too.

#### **Determination of the Scope and Content of the Prior Art (MPEP §2141.01)**

The teachings of Jakupovic, Subramniam, and Nakashima are set forth above.

#### **Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)**

Jakupovic does not explicitly teach of a process of forming progesterone or 3-ketodesogestrel crystal particles. This deficiency is cured by the teachings of Chen.

Chen teaches a novel pharmaceutical formulation that provides for increased absorption and bioavailability of active agents, particularly active agents that are administered orally (column 8, lines 58-61). Chen teaches a list of active agents that includes preferred sex hormones such as progestins, such as, **3-ketodesogestrel** (column 10, line 24). Chen teaches that the active agent can be dissolved in appropriate solvent and subjected to crystallization (column 54, lines 35-37 and claim 8) via precipitation by antisolvent (column 54, lines 50-54). Chen teaches an illustrative example of a pharmaceutical formulation comprising **progesterone** (column 73, example 48).

**Finding of Prima Facie Obviousness Rationale and Motivation  
(MPEP §2142-2143)**

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to prepare a pharmaceutical formulation of 3-ketodesogestrel or progesterone via the utilization of crystallization using precipitation by antisolvent, because as discussed above Chen teaches that the active agent can be dissolved in appropriate solvent and subjected to crystallization via precipitation by antisolvent to form pharmaceutical solid particles of **3-ketodesogestrel** or progesterone. Moreover, one of ordinary skill in the art would also recognize that substituting one anti-inflammatory agent such as progesterone as evidenced by Nakagawa for another (e.g. budesonide) is obvious because the selection of a known material based on its suitability for its intended use supports a determination of prima facie obviousness (MPEP § 2144.07). A skilled artisan would have had a reasonable expectation of success because

Art Unit: 1619

the anti-inflammatory agents will serve the same intended function healing inflammation after being crystallized through the same process.

**Claims 1, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jakupovic (US Patent No. 6,221,398), Subramniam (US Patent No. 6,113,795), Nakashima (US Patent No. 5,326,484), and Maruyama (US Patent No 5,512,092).**

#### **Applicant Claims**

The claimed subject matters of instant claim 1 are set forth above. Instant claim 11 recites a process according to claim 1, wherein the solid particles are coated with a coating solution. Instant claim 12 recites a process according to claim 11, wherein the prepared solid composition comprises particles having a core coated with a coating material which comprise a pharmaceutical compound.

#### **Determination of the Scope and Content of the Prior Art (MPEP §2141.01)**

The teachings of Jakupovic, Subramniam, and Nakashima are set forth above.

#### **Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)**

Jakupovic does not teach of a process of coating the solid particles, which are formed via the above discussed process, by passing a liquid medium comprising dissolved coating material through a membrane into a suspension of particles. This deficiency is cured by the teachings of Maruyama.

Maruyama teaches a method for preparing an aqueous emulsion for coating solid pharmaceutical preparations comprising the steps of dissolving a cellulosic polymer in a mixed solvent of water and an organic solvent capable of being admixed with water in any rate to give a polymer solution, self-emulsifying the polymer solution by mixing with water and then concentrating the resulting emulsified stock solution. The concentration is carried out by removing a part of the liquid components while passing it through a membrane for ultrafiltration until the polymer concentration of the resulting emulsion reaches a level of not less than 7% by weight (see Abstract). Maruyama teaches the coating treatment is performed by spraying to the solid particles (column 4, line 21).

**Finding of Prima Facie Obviousness Rationale and Motivation  
(MPEP §2142-2143)**

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Jakupovic by coating the solid particles, because, Maruyama as discussed above teaches coating pharmaceutical solids utilizing drug coating materials. One of ordinary skilled in the art would be motivated to do the coating because it will serve not only protect a drug having low resistance to acids from the attack thereof in the stomach, but also protect the gastric mucous membrane from the attack of the drug which may stimulate and damage the wall of the stomach and is dissolved after the arrival at the intestines wherein the pharmaceutical preparation shows its desired pharmacological action as described by Maruyama et al. With regard to passing the coating solution through a membrane one of ordinary skilled in the art would be motivated to do that, because the step would help to concentrate and adjust the concentration of the coating solution to a needed level as also demonstrated by

Maruyama et al.. A skilled artisan would have had a reasonable expectation of success in combining the references, because all references are concerned with pharmaceutical solid particles.

**Claims 1, 18, and 19 under 35 U.S.C. 103(a) as being unpatentable over Jakupovic (US Patent No. 6,221,398), Subramniam (US Patent No. 6,113,795), Nakashima (US Patent No. 5326484), and Saim (US Patent No 6,858,166).**

#### **Applicant Claims**

The claimed subject matters of instant claims 1 and 18 are set forth above. Instant claim 19 recites a process according to claim 18, wherein the dosage form is a tablet.

#### **Determination of the Scope and Content of the Prior Art (MPEP §2141.01)**

The teachings of Jakupovic, Subramniam, and Nakashima are set forth above.

#### **Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)**

Jakupovic does not teach the dosage in the form of a tablet. This deficiency is cured by the teachings of Saim.

Saim teaches a method for solute particle precipitation, retention and dispersion in a carrier material by taking advantage of the unique properties of pressurized gaseous (e.g. supercritical) fluids to precipitate solute particles from solution and by effectively retaining and dispersing the precipitated particles in a carrier material having good flow and handling properties (column 5, lines 51-58). Saim teaches that the blends, granulations and partially or fully coated carrier materials, or mixtures thereof, produced by the methods are particularly suited for



Art Unit: 1619

pharmaceutical processing into **various pharmaceutical formulations and dosage forms, such as tablets and capsules** (column 6, lines 42-46).

**Finding of Prima Facie Obviousness Rationale and Motivation  
(MPEP §2142-2143)**

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Jakupovic by preparing the dosage in the form of tablets, because Saim teaches that such particles can be prepared in the form of tablets. One of ordinary skilled in the art would be motivated to prepare the dosage in the form of tablets, because tablets are conventionally known pharmaceutical dosage form. A skilled artisan would have had a reasonable expectation of success in combining the references, because both references are concerned with pharmaceutical solid particles.

**Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867.

The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1619

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa

1/27/11

/Cherie M. Woodward/  
Primary Examiner, Art Unit 1647